

Election/Restriction

Applicants elected Group I in the reply filed on July 10, 2006. Applicants have herein designated the non-elected invention (i.e. the method claims) as withdrawn.

Applicants submit that once the compounds of the present invention are found to be novel, then the other Groups defined by the Examiner that contain any compositions of matter containing those compounds should also be found to be novel and rejoined. Likewise, pursuant to linking claim practice, at least one of the method claims should be rejoined.

Furthermore, Applicants affirm their right to file one or more divisional applications with respect to any of the non-elected subject matter.

In the 5/10/06 Office Action, the Examiner stated the following on page 3:

The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound (or set of compounds), but may also include additional compounds which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first Office Action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with process of using said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined (emphasis added). Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case.

The Examiner has now designated the scope of compounds in the Office Action mailed 10/12/06 but the Examiner has not properly set forth the basis for designating the scope of the compounds i.e. the Examiner has not set forth the specific class(es) and subclass(es) that formed the basis for the designation.

Applicants request reconsideration and withdrawal of the restriction requirement with respect to Group I now that this group has been fully designated by the Examiner. The Examiner cites *In re Harnisch* and *Ex parte Hozumi* (on page 2 of the 5/10/06 Office Action). The Office Action recited that a restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial feature disclosed as being essential to that utility.

In the instant case, the Examiner has not provided any comment regarding how applicants' claimed invention does not (1) share a common utility or (2) share a substantial structural feature. Furthermore, the Examiner has provided no evidence of dissimilar properties among the members of the Markush group justifying restriction, but merely observed that each of the groups of compounds, as defined by the Examiner, would involve different fields of search. However, the mere fact that different fields of search are involved does not establish that a Markush group is improper. In particular, the PTO Board of Appeals stated "the fact that [six] different fields of search are involved does not establish that the Markush group is improper." See *Ex Parte Brouard et al.*, 201 USPQ 538, 540.

In discussing the propriety of imposing restriction requirements to a single claim under § 121, the CCPA has stated:

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of § 112.

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. ... If, however, a single claim is divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since

the sub-genera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In re Weber, Soder, and Boksay, 198 USPQ 328, 331 (CCPA 1978)

Thus, the improper imposition of the restriction requirement is contrary to the Applicants' statutory right to claim their invention as they see fit, and is clearly contrary to the law as stated in the Weber case.

Applicants respectfully assert that the Examiner improperly implied the two prong test of MPEP 803.02 and *In re Harnisch* in determining that Applicants' generic structure lacks unity of invention.

Under MPEP 803.02, it is improper for the Examiner to refuse to examine that which applicants regard as their invention, unless the subject matter lacks unity of invention. Unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature as being essential to that utility. In considering the propriety of a Markush grouping, the compounds must be considered as a whole and not broken down into elements or other components. *In re Harnisch*, 206 USPQ 300, 305.

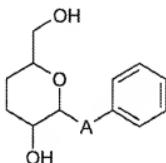
The *Harnisch* court also cited with approval *In re Jones*, 74 USPQ 149, in which the court stated:

It is evident that in any Markush group, the compounds which are included will differ from each other in certain respects. In determining the propriety of the grouping, these differences must, to some extent, be weighed against the similarities and, ... "whether a group is proper must be decided in view of the facts of each particular case." The inclusion in Markush groups of compounds which differed widely in some respects has been permitted. [citations omitted]. ... In the instant case no authority was cited by either of the tribunals of the Patent Office in support of the conclusion that the compounds

called for by claims 1 and 6 are so dissimilar in their properties as to be repugnant to principles of scientific classification.

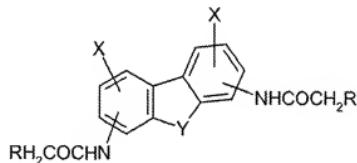
Id at 151.

Applicants submit that their claimed invention encompasses compounds represented by a genus having a common structural similarity, i.e., the compound of formula



and that the claimed compounds belong to a genus having a common use, i.e. the treatment of a patient suffering from a disease state capable of being modulated by an SGLT effect. Therefore, Applicants submit that the genus meets the two-pronged test of *In re Harnisch*, and should not be restricted.

Furthermore, *Ex parte Dahlen and Zwigmeyer* supports that there can be variations in a variable in a ring structure that do not support an Election/Restriction requirement. In *Ex parte Dahlen and Zwigmeyer*, 42 USPQ 208, (POBA, 1939), propriety was recognized in a Markush compound of the following formula



wherein there was variability in a constituent variable in the core structure, i.e., Y. That variable was defined in Markush format as a bivalent bridge radical that included $-\text{CH}_2-$, $-\text{CO}-$, $-\text{C}=\text{C}-$, $-\text{CH}_2\text{CH}_2-$, $-\text{NH}-$, $-\text{N-alkyl-}$, $-\text{O}-$, $-\text{S}-$, $-\text{N=N-}$, $-\text{N=NO-}$, $-\text{SO}_2-$ and $-\text{COCO-}$. Particularly noteworthy regarding that compound was that the Markush grouping was found to be acceptable even though the variable provided for molecular variations in the size and classification of tricyclic ring system thereof, i.e., the central ring could consist of 5 to 6

members and form one cyclopentadienyl ring, one cyclohexadienyl ring, one phenyl ring, and five different heteroaryl rings. Thus, variations in the classification groupings encompassed by the compound did not provide sufficient basis for restriction.

Thus, in view of *In re Harnisch*, *Ex parte Dahlen* and *Zwilmeyer* and *Ex parte Brouard* et al., Applicants submit that the Examiner should not require restriction of the Markush grouping.

In view of the aforesaid comments regarding MPEP § 803.02 and case law cited by Applicants, Applicants request the reconsideration and withdrawal of the Restriction Requirement. Applicants also request that the arguments regarding the impropriety of the Election/Restriction be specifically addressed, if the Election/Restriction is maintained. Furthermore, Applicants request that they be provided with the opportunity to respond to any new bases, if any, made in support of the Election/Restriction.

Alternatively, if the Examiner will not withdraw the Restriction Requirement, Applicants request that the Examiner revise the Restriction. Applicants specifically request that the Examiner consider expanding the scope of the definitions to include the following:

R1, R2 are each independently OH, F or H with the proviso that
when R1 is F, R2 cannot be OH;
when R1 is OH, R2 cannot be F; and
when R1 is OH, R2 cannot be OH;

R3 is OH or F,
with the proviso that at least one of said R1, R2, R3 radicals must be F;

A is O;

R4, R5, R6 are each independently hydrogen, OH, (C₁-C₄)-alkoxy, CF₃, (C₁-C₄)-alkyl, F, Cl, Br or I

B is -CH₂-, -C₂H₄-, -C₃H₆-, -CH(OH)-, -(C=O)-, -CO-NH-CH₂-, -CO-CH₂-CH₂-, -O- or -NH-;

n is 2 or 3;

- Cyc1 is an unsaturated 6-membered ring, wherein one carbon atom of said 6-membered ring may be replaced by N, or an unsaturated 5-membered ring, wherein one carbon atom of said 5-membered ring may be replaced by S;
- R7, R8, R9 are each independently hydrogen, OH, (C₁-C₄)-alkyl, (C₁-C₇)-alkoxy, OCF₃ or halogen; or
- R8 and R9 taken together form the radicals -CH=CH-O-, -CH₂-CH₂-O-, -CH=CH-CH=CH- or -O-(CH₂)_p-O- wherein p is 1 or 2, and, with the carbon atoms to which they are attached, form a 5- or 6-membered ring, and, in such instance, R7 is preferably methyl, ethyl, methoxy, F, Cl, Br or hydrogen.

Claim Rejections – 35 USC §112

The Examiner has rejected claims 1-7 under 35 USC 112, first paragraph. The Examiner alleges that the specification, while being enabling for the compounds outlined in paragraph 2 of the Office Action, does not reasonably provide enablement for the invention as now claimed. Applicants respectfully disagree. The Examiner asserts that the instantly claimed invention is highly unpredictable, requiring each embodiment to be individually assessed for physiological activity. The Examiner states that the level of skill in the art is high. Given the high state of skill in the art, Applicants respectfully submit that the specification provides ample teaching regarding how to make and use the compounds of the instant invention. The testing protocol is set forth on page 31 and working examples can be found throughout the specification.

The Examiner contends that the properties, bonding, and structures of the variables and/or rings is different. This fact alone is not *prima facie* evidence that the claims lack enablement. It is not evidence that the teaching of the specification is not commensurate with the scope of the claims. It may be true that it is not entirely predictable which compounds will be active in the testing protocol. However, looking at the level of skill in the art and the teaching of the specification as a whole, it would be reasonable to conclude that while the scope of the claims may encompass non-operative embodiments, the experimentation needed to determine the operative embodiments and to use those

embodiments would not be undue. Therefore, Applicants assert that any enablement or scope rejection in this case is improper.

Respectfully submitted,



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